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A comparison of the laryngeal mask airway with the oropharyngeal airway and facemask to achieve manual ventilation in children as performed by critical care and anaesthetic nurses

Submission date 14/03/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 02/05/2006	**Overall study status** Completed	
Last Edited 07/12/2010	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 7

Study information

Scientific Title

Acronym
PAWS

Study objectives
Does the laryngeal mask airway (LMA) have a superior efficacy in achieving manual ventilation (breathing) compared with the current recommended technique for children who are not breathing, when used by critical care and anaesthetic nurses?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Oxford Research Ethics Committee B on 17/08/2005, reference number: 05/Q1605/104

Study design
Randomised, controlled, efficacy study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Children undergoing ASA I or II surgery or an MRI scan

Interventions
Insertion of a LMA airway versus oropharyngeal airway. Patients have both airways inserted, however the order of the insertion is randomised, immediately prior to inserting the airway, the nurse opens a sealed opaque envelope generated using a table of random numbers which states which airway should be inserted first.

Intervention Type

Other

Phase
Not Specified

Primary outcome measure
Chest excursion

Secondary outcome measures
1. Minute volume achieved by nurse and anaesthetist
2. Time to first breath
3. Mean inhaled and exhaled tidal volume

Overall study start date
01/09/2005

Completion date
01/09/2006

Eligibility

Key inclusion criteria
1. Patients aged between 6 months and 8 years scheduled for anaesthesiologists physical status (ASA) I and II surgery or a magnetic resonance imaging (MRI) scan
2. Patients who would routinely have an LMA inserted

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Months

Upper age limit
8 Years

Sex
Both

Target number of participants
70

Key exclusion criteria
1. Patients with an expected difficult airway
2. Patients with oesophageal reflux
3. Patients under 6 months
4. Patients 9 years or older

Date of first enrolment
01/09/2005

Date of final enrolment
01/09/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nuffield Department of Anaesthetics
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
Oxford Radcliffe Hospitals NHS Trust (UK)

Sponsor details
Research and Development
Manor House
Headley Way
Oxford
England
United Kingdom
OX3 9DZ

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03h2bh287

Funder(s)

Funder type
Charity

Funder Name
The Resuscitation Council UK

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2007		Yes	No